2018 Current Fiscal Year Report: Gastrointestinal Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Gastrointestinal Drugs Advisory Committee	874

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/03/2018	03/03/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
The committee discussed supplemental new drug application (sNDA) 203214, supplement 18, XELJANZ (tofacitinib) 5 mg and 10 mg tablets, submitted by Pfizer Inc., proposed for the treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response or intolerance to corticosteroids, azathioprine, 6-mercaptopurine or tumor necrosis factor (TNF) inhibitor therapy.	03/08/2018	03/08/2018
The Gastrointestinal Drugs Advisory Committee and Pediatric Advisory Committee jointly met to discuss new drug application (NDA) 209904, for stannsoporfin injection, for intramuscular use, submitted by InfaCare Pharmaceutical Corporation, proposed for the treatment of neonates greater than or equal to 35 weeks of gestational age with indicators of hemolysis who are at risk of developing severe hyperbilirubinemia.	05/03/2018	05/03/2018

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$7,834.00	$19,686.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$164,212.00	$166,799.00
18a(4). Personnel Pmts to Non-Member Consultants	$4,191.00	$9,843.00

18b(1). Travel and Per Diem to Non-Federal Members	$13,247.00	$31,974.00
18b(2). Travel and Per Diem to Federal Members	$1,005.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$6,621.00	$9,972.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$52,554.00	$59,127.00
18d. Total	$249,664.00	$297,401.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are authorities in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. The committee includes one technically qualified voting member who is identified with consumer interests. The Committee may include one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee met twice during FY-18. On March 8, 2018, the committee discussed supplemental new drug application (sNDA) 203214, supplement 18, XELJANZ (tofacitinib) 5 mg and 10 mg tablets, submitted by Pfizer Inc., proposed for the treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response or intolerance to corticosteroids, azathioprine, 6-mercaptopurine or tumor necrosis factor (TNF) inhibitor therapy. The committee voted in the affirmative (Yes 15 – No 0 – Abstain 0) for the inclusion of the 10 mg BID dosing regimen for the proposed patient population in the product label. The panel commented that patients with ulcerative colitis are a patient population desperate for new treatment options, and it would be better to try treating with tofacitinib for a little longer than to abandon a potentially efficacious therapy at 8 weeks, when patients may have no other available therapeutic options. Additionally, the committee voted in the affirmative (15 Yes – 0 No – 0 Abstain) that the benefits of having tofacitinib 10 mg BID as an option outweigh the safety risks observed in clinical trials. It was discussed that it would be helpful for the Applicant to provide information regarding when a 5 mg BID dosing regimen is appropriate for use in patients with history of TNF blocker failure. Action: The Agency approved the product for the new supplemental indication. On May 3, 2018, the

committees discussed new drug application (NDA) 209904, for stannsoporfin injection, for intramuscular use, submitted by InfaCare Pharmaceutical Corporation, proposed for the treatment of neonates greater than or equal to 35 weeks of gestational age with indicators of hemolysis who are at risk of developing severe hyperbilirubinemia. The committee voted in opposition (2 Yes – 21 No – 1 Abstain) when asked if the long-term and short-term safety profile of stannsoporfin in the proposed indicated population support approval. The committee discussed that there are inadequate data to support the long-term and short-term safety profile of stannsoporfin. Additionally, the committee voted in opposition (0 Yes without a REMS – 3 Yes with a REMS – 21 No) when asked if the overall risk-benefit profile of stannsoporfin support approval. The committee discussed that there may be a group of patients who may benefit from this drug, but that the specific population needs to be more clearly identified and studied. Agency Action: The Agency is currently evaluating recommendations made during the advisory committee. It is expected that the committee will meet 2-3 times during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the Committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions withstand intense public scrutiny. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

No reports are required for this committee.

Designated Federal Officer

Jay R. Fajiculay Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Assis, David	06/29/2016	06/30/2020	Assitant Professor, Yale School of Medicine	Special Government Employee (SGE) Member
Chang, Lin	07/01/2015	06/30/2019	Professor of Medicine, UCLA	Special Government Employee (SGE) Member
Coffey, Christopher	03/19/2018	06/30/2021	Director, Clinical Trials Statistical and Data Management Center, University of Iowa	Special Government Employee (SGE) Member
Feagins, Linda	07/01/2014	06/30/2018	Assistant Professor of Medicine, Dallas Veterans Affairs Medical Center	Regular Government Employee (RGE) Member
Hugick, Joy	03/19/2018	06/30/2021	CONSUMER REPRESENTATIVE - Public Health Policy and Communication Consultant, Simply Joy, LLC	Special Government Employee (SGE) Member

Khurana, Sandeep	07/01/2015	06/30/2019	Associate Professor of Medicine, Georgia Regent University	Special Government Employee (SGE) Member
Lai, Jennifer	08/06/2018	06/30/2022	Director of Gastroenterology/Hepatology, University of Caifornia - San Francisco	Special Government Employee (SGE) Member
Lebwohl, Benjamin	07/01/2017	06/30/2021	Associate Professor, Columbia University College of Physicians & Surgeons	Special Government Employee (SGE) Member
Levine, Douglas	03/30/2016	10/31/2019	Manager and Sole Member, DSL Consulting, LLC	Representative Member
Pardi, Darrell	05/23/2016	06/30/2019	Vice Chair, Mayo School of Graduate Medical Education	Special Government Employee (SGE) Member
Raufman, Jean-Pierre	07/01/2015	06/30/2019	Professor of Medicine, Univ of Maryland School of Medicine	Special Government Employee (SGE) Member
Rosen, Rachel	07/01/2016	06/30/2020	Director and Assistant Professor of Pediatrics, Boston Children's Hospital	Special Government Employee (SGE) Member
Strate, Lisa	07/01/2017	06/30/2021	Associate Professor, University of Washington School of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 13

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Gastrointestinal Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	

Increased customer satisfaction	☑
Implementation of laws or regulatory requirements	☑
Other	☐

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

The utilization of the Gastrointestinal Drugs Advisory committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

22

Number of Recommendations Comments

The committee made 22 recommendations from FY-03 through FY-18. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

77%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

9%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

NA